

What we claim is:

1. A process for the preparation of a poorly water soluble drug in solid dispersion comprising
  - a) blending the drug with a carrier;
  - b) dissolving a surfactant and a plasticizer/solubilizer in water;
  - c) spraying the surfactant-plasticizer/solubilizer solution onto the drug/carrier mixture in a fluid bed granulator;
  - d) extruding the resulting granulation through a twin screw extruder with at least one heating zone; and,
  - e) milling the extrudate to a powdery mass of the solid drug dispersion.
2. The process of claim 1 wherein said drug is selected from the group consisting of acetohexamide, ajamaline, amylobarbitone, bendrofluozide, benzbromarone, benzonatate, benzylbenzoate, betamethazone, chloramphenicol, chlorpropamide, chlorthalidone, clofibrate, corticosteroids, diazepam, dicumerol, digitoxin, dihydroxypropyltheophylline, ergot alkaloids, ethotoin, frusemide, glutethimide, griseofulvin, hydrochlorothiazide, hydrocortisone, hydroflumethiazide, hydroquinone, hydroxyalkyl-xanthines, indomethacin, isoxsuprine hydrochloride, ketoprofen, khellin, meprobamate, nabilone, nicotainamide, nifedipine, nitrofurantoin, novalgin, nystatin, papaverine, paracetamol, phenylbutazone, phenobarbitone, prednisolone, prednisone, primadone,

reserpine, romglizone, salicylic acid, spiranolactone, sulphabenzamide, sulphadiazine, sulphamethoxydiazine, sulphamerazine, succinylsulphathiazole, sulphamethizole, sulphamethoxazole, sulphathiazole, sulphisoxazole, testosterone, tolazoline, tolbutamide, trifluoperazine, trimethaprim and mixtures thereof.

3. The process of claim 2 wherein said carrier is selected from the group consisting of polyvinyl pyrrolidone, high molecular weight polyethylene glycol, urea, citric acid, vinyl acetate copolymer, Eudragit® acrylic polymers, succinic acid, sugars and mixtures thereof.
4. The process of claim 3 wherein said plasticizer/solubilizer is selected from the group consisting of low molecular weight polyethylene glycol, propylene glycol, glycerin, triacetin, triethyl citrate, sugar alcohols and mixtures thereof.
5. The process of claim 4 wherein said surfactant is selected from the group consisting of Tween, Span, Pluronic, polyoxyethylene sorbitol esters, monodiglycerides, polyoxyethylene acid polyoxyethylene alcohol and mixtures thereof.
6. The process of claim 5 wherein said granulation is extruded at a temperature less than the decomposition point of said drug.
7. The process of claim 6 wherein said drug and carrier are mixed in ratios of from about 1:9 to about 5:1 respectively, on a percent weight basis.
8. The process of claim 7 wherein said drug and carrier are mixed in a ratio of from about 3:1 to about 1:3 respectively, on a percent weight basis.

9. A solid pharmaceutical dispersion with improved solubility characteristics consisting essentially of a poorly water soluble drug and;
- a) a carrier selected from the group consisting of polyvinyl pyrrolidone, high molecular weight polyethylene glycol, urea, citric acid, Eudragit® acrylic polymers, succinic acid and mixtures thereof and,
  - b) a solubilizer/plasticizer selected from the group consisting of polyols, phthalate esters, glycerol esters, citrate esters, sugar alcohols and mixtures thereof.
10. The solid pharmaceutical dispersion of claim 9 wherein said poorly water soluble drug is selected from the group consisting of acetohexamide, ajamaline, amylobarbitone, bendrofluozide, benzbromarone, benzonatate, benzylbenzoate, betamethazone, chloramphenicol, chlorpropamide, chlorthalidone, clofibrate, corticosteroids, diazepam, dicumerol, digitoxin, dihydroxypropyltheophylline, ergot alkaloids, ethotoin, frusemide, glutethimide, griseofulvin, hydrochlorothiazide, hydrocortisone, hydroflumethiazide, hydroquinone, hydroxyalkyl-xanthines, indomethacin, isoxsuprine hydrochloride, ketoprofen, khellin, meprobamate, nabilone, nicotainamide, nifedipine, nitrofurantoin, novalgin, nystatin, papaverine, paracetamol, phenylbutazone, phenobarbitone, prednisolone, prednisone, primadone, reserpine, romglizone, salicylic acid, spiranolactone, sulphabenzamide, sulphadiazine, sulphamethoxydiazine, sulphamerazine, succinylsulphathiazole, sulphamethizole, sulphamethoxazole, sulphathiazole,

sulphisoxazole, testosterone, tolazoline, tolbutamide, trifluoperazine, trimethaprim and mixtures thereof.

11. The solid pharmaceutical dispersion of claim 10 wherein said drug and carrier are formulated in ratios of from about 1:9 to about 5:1 respectively, on a percentage weight basis.
12. The solid pharmaceutical dispersion of claim 11 wherein said drug and said carrier are formulated in ratios of from about 3:1 to about 1:3, respectively on a percentage weight basis.
13. A solid pharmaceutical dispersion with improved solubility characteristics comprised of a poorly water soluble drug and a carrier produced by the process consisting of:
  - a) mixing said drug and the carrier in a ratio of approximately 1:9 to about 5:1 respectively, on a percent weight basis;
  - b) spraying onto said mixture a solution consisting of a plasticizer/solubilizer, and optionally, a surfactant;
  - c) extruding the resultant granulation in a twin screw extruder with at least one heating zone; and
  - d) milling the extrudate to a powdery mass.
14. The solid pharmaceutical dispersion of claim 13 wherein said drug is selected from the group consisting of acetohexamide, ajamaline, amylobarbitone, bendrofluozide, benzbromarone, benzonatate, benzylbenzoate, betamethazone, chloramphenicol,

chlorpropamid , chlorthalidone, clofibrate, corticosteroids, diazepam, dicumerol, digitoxin, dihydroxypropyltheophylline, ergot alkaloids, ethotoin, frusemide, glutethimid , griseofulvin, hydrochlorothiazide, hydrocortisone, hydroflumethiazide, hydroquinone, hydroxyalkyl-xanthines, indomethacin, isoxsuprine hydrochloride, ketoprofen, khellin, meprobamate, nabilone, nicotainamide, nifedipine, nitrofurantoin, novalgin, nystatin, papaverine, paracetamol, phenylbutazone, phenobarbitone, prednisolone, prednisone, primadone, reserpine, romglizone, salicylic acid, spiranolactone, sulphabenzamide, sulphadiazine, sulphamethoxydiazine, sulphamerazine, succinylsulphathiazole, sulphamethizole, sulphamethoxazole, sulphathiazole, sulphisoxazole, testosterone, tolazoline, tolbutamide, trifluoperazine, trimethaprim and mixtures thereof.

15. The solid pharmaceutical dispersion of claim 14 wherein said carrier is selected from the group consisting of polyvinyl pyrrolidone, high molecular weight polyethylene glycol, urea, citric acid, vinyl acetate copolymer, Eudragit® acrylic polymers, succinic acid, sugars and mixtures thereof.
16. The solid pharmaceutical dispersion of claim 15 wherein said plasticizer/solubilizer is selected from the group consisting of low molecular weight polyethylene glycol, propylene glycol, glycerin, triacetin, triethyl citrate, sugar alcohols and mixtures thereof.
17. The solid pharmaceutical dispersion of claim 16 wherein said surfactant is selected from the group consisting of Tween, Span, Pluronic, polyoxyethylene sorbitol esters, polyoxyethylene acid, polyoxyethylene alcohols and mixtures thereof.

18. The solid pharmaceutical dispersion of claim 17 wherein said extrusion is carried out at a temperature below the decomposition point of said drug.
19. The solid pharmaceutical dispersion of claim 18 wherein said extrusion occurs at a rate of approximately 2 gm/sec. to about 7 gm/sec.